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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/628,112	07/27/2000	Se-Jin Lee	JHU1120-11	2658

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EXAMINER
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ALLEN, MARIANNE P

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 06/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/628,112

Applicant(s)

LEE ET AL.

Examiner

Marianne P. Allen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 34, 37, 40, 43-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 44 and 45 is/are allowed.
- 6) ☒ Claim(s) 1, 34, 37, 40, 43, 46 and 47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Applicant's arguments filed 3/30/06 have been fully considered.

Claims 1, 34, 37, 40, and 43-47 are pending and under consideration. Claims 46-47 have been newly introduced.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Specification***

Applicant is again requested to update the status of the co-pending applications referenced in the specification.

### ***Claim Objections***

Claims 1, 34, 37, 40, and 43 are objected to because of the following informalities:  
Claims 1, 34, and 40 are missing the closing parenthesis following “(SEQ ID NO: 4” and “SEQ ID NO: 18.” Claims 37 and 43 recite “from the group consisting of as set forth in SEQ ID NO: 2.” This appears to be a word processing error and appears that “as set forth in” was intended to be deleted. Appropriate correction is required.

### ***Double Patenting***

The terminal disclaimer filed on 9/12/02 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 5,827,733 has been reviewed and is accepted. The terminal disclaimer has been recorded.

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Claims 1, 34, 37, 40, and 43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 20 of copending Application No. 10/997,809. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim of the co-pending application is directed to GDF-8 proteins from chicken corresponding to instant SEQ ID NO: 8.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant is requested to identify all related co-pending applications with claims directed to polypeptides corresponding to or substantially similar to those in the present claims.

Applicant is reminded that they must maintain a clear line of demarcation between applications.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 34, 37, 40, 43, 46, and 47 are rejected under 35 U.S.C. 102(e) as being anticipated by Barker et al. (U.S. Patent No. 6,369,201 B1).

Particular embodiments embraced by claim 1 are substantially purified peptides consisting of about amino acids 1-20 of SEQ ID NOS: 2, 4, 6, 8, 10, 12, 14, 16, 18, or 20 (the

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promyostatin signal peptide domain). These claims require signal peptide activity. These concepts are not disclosed by parent application 09/124,180.

Particular embodiments embraced by claims 34, 37, and 46 are substantially purified peptides consisting of amino acids 20-262 of SEQ ID NOS: 2, 8, 10, 12, 14, 16, 18, or 20 or consisting of about amino acids 20-263 of SEQ ID NOS: 4 or 6 (the promyostatin prodomain). These claims require myostatin binding activity. These concepts are not disclosed by parent application 09/124,180.

Particular embodiments embraced by claims 40, 43, and 47 are substantially purified peptides consisting of about amino acids 268-375 of SEQ ID NOS: 4 or 6 or consisting of amino acids 267-374 of SEQ ID NOS: 2, 8, 10, 12, 14, 16, 18, or 20, (the promyostatin myostatin domain). These claims require muscle growth inhibitory activity. These concepts are not disclosed by parent application 09/124,180.

The amino acid residue ranges set forth in claims 44 and 45 are not disclosed in parent application 09/124,180. It is further noted that the zebrafish and salmon sequences are not provided by this parent application.

As such, benefit to the filing date of parent application 09/124,180 is denied for all claims. The effective filing date for these claims is considered to be 27 July 2000.

Barker et al. is valid prior art against the instant claims as this application was filed on 18 February 1999.

Barker et al. discloses the full length sequences for human, murine, rat, chicken, baboon, bovine, porcine, ovine, turkey, and zebrafish promyostatin polypeptides. Barker's SEQ ID NOS:

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29, 27, 28, and 30 corresponding directly to instant SEQ ID NOS: 4, 6, 2, and 10, respectively. Barker's SEQ ID NOS: 31-34 and 36 have a conservative substitution in a single position with respect to instant SEQ ID NOS: 12, 14, 16, 8, and 20, respectively. Barker's SEQ ID NO: 35 has two mismatches to instant SEQ ID NO: 18. Particular fragments of these polypeptides are also disclosed. See at least Figure 1A-1D and column 3, lines 25-45. Note that none of the mismatches occurs in the promyostatin myostatin domain and only one mismatch (for SEQ ID NO: 18) occurs in the promyostatin signal peptide domain. However, as the mismatch in SEQ ID NO: 18 is at amino acid three, this is considered to be within the claim limitation of "about 1-20."

This disclosure anticipates the instant claims as the claims all use "comprising" or open language and include the full length sequences as well as the fragments disclosed by Barker et al.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712.

The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Marianne P. Allen  
Primary Examiner  
Art Unit 1647

mpa